

**DRUG DELIVERY VIA PUNCTAL PLUG****FIELD AND BACKGROUND OF THE INVENTION**

- [0001]** The present invention relates generally to the field of medicine, and in particular to a new and useful method and apparatus for administering an active agent, i.e. a medicine or medication, to a subject by transdermal or other surface absorption of the agent into the tissues in and around one or both eyes of the subject.
- [0002]** Punctal plugs are known which are made in suitable dimensions and of suitable materials to be removably inserted into the upper and/or lower punctal apertures or punctum of the eye, to block the opening and the canaliculus communicating therewith, to prevent drainage of lacrimal fluid (tears). Such plugs are known to be made of suitable materials, such as polymers, for example polytetrafluorethylene (known by the trademark TEFLON), or hydroxyethylmethacrylate (HEMA), hydrophilic polymer, methyl methacrylate, or silicon, or even of stainless steel or other inert metal material.
- [0003]** It is also known to apply an active agent such as nicotine or a birth control drug, to the inner surface of a patch which can be worn against the skin of a subject for transdermally administering the active agent to the subject.

### **SUMMARY OF THE INVENTION**

- [0004]** It is an object of the present invention to provide a method and an apparatus for administering an active agent to a subject by applying the active agent to at least one surface of an ocular implant such as a punctal plug, and installing the implant, e.g. inserting the punctal plug into a punctal aperture of the subject.
- [0005]** If the active agent or drug is meant for treating the tissues at the walls of the canaliculus, for example, the drug is applied only to inner surfaces of the plug that are adapted to be in contact with or near the tissues of the canaliculus. The presence of tears is highly advantageous as a natural vehicle or carrier for the agent.
- [0006]** If the active agent or drug is meant for treating the eye itself, the drug is applied only to outer surfaces of the implant or plug that are adapted to be outside the canaliculus. Here the presence of previously secreted tears or a tear pool is again advantageous as a natural vehicle or carrier for the agent.
- [0007]** Any or all surfaces of the implant may carry the active agent there the desire is simply to have the agent enter the subjects blood stream via the tissues in and around the eye.
- [0008]** The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the invention, its operating advantages and specific objects attained by its uses, reference is made to the accompanying drawings and descriptive matter in which preferred embodiments of the invention are illustrated.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

- [0009] In the drawings:
- [0010] Fig. 1 is a schematic perspective view of an ocular implant in the form of a punctal plug according to the present invention; and
- [0011] Fig. 2 is a perspective view of the area around the eye with other embodiments of the invention.

### **DESCRIPTION OF THE PREFERRED EMBODIMENT**

- [0012] Referring now to the drawing, Fig. 1 shows a punctal plug generally designated 10, having a stem 12 for insertion into the punctal aperture 20 of an eye 24, and along the canaliculus 22 communicating with the aperture.
- [0013] Plug 10 has a large stopper structure 14 connected to the outer end of stem 12 for seating against the aperture 20 and sealing the canaliculus 22 against the flow of tears onto the surface of the eye or eyeball 24.
- [0014] Fig. 2, where the same of similar numerals are used to designate functionally similar parts, illustrates an eye 24 communicating with upper and lower canaliculi 22a and 22b, each with their own implant 10a and 10b. Implant 10a is a substantially cylindrical and solid collagen plug that has been inserted into the upper punctum or tear duct 20a, to block the flow of tears while lower implant 10b is hollow like a straw for the passage of tears. Implant 10b includes a tapered shaft or stem 12a with a flared open end 12b immobilized at the lower punctum 20b. A mushroom shaped inner stopper 14a is formed at the opposite end of shaft 12a for further setting the location of the implant in the tear duct.
- [0015] One of the embodiments illustrated in Fig. 2, e.g. the upper implant, may

include a hollow core of the plug and another, e.g. the lower one, may include a hollow core filled with medication.

**[0016]** The active agent, e.g. a medicine or medication is applied, e.g. in one or more bands of polymer material 16 at the inner end of the stem, or at 18 on the outer end of the stopper 14 in the embodiment of Fig. 1, or over some or all of the surfaces of the implants of Fig. 2, or otherwise. Polymer that is absorbent to the agent is preferable so that sufficient agent is present and available for discharge into the surrounding tissues. A porous or absorbent material can alternatively be used to make up the entire plug or implant which can be saturated with the active agent.

**[0017]** The hollow implant 10b of Fig. 2 is also particularly useful in that the active agent can be applied to, or is otherwise available at the inner surface or interior of the implant, and is uniquely structured to pass tears and thus administer the active agent to the tear stream in a fashion that is controlled by the flow of tears which thus act as the carrier for the agent. Unlike the usual tear stopping punctal plug, the hollow implant of the present invention provides a very different drug administering method, scheme and structure.

**[0018]** Non-limiting examples of the active agents or medications which are appropriate for use with the invention include, for example only: topical prostaglandin derivatives such as latanoprost, travaprost and bimatoprost used for the topical treatment of glaucoma. Also a treatment for corneal infections is appropriate using ciprofloxacin, moxifloxacin or gatifloxacin. Systemic medications useful for this invention are those used for hypertension such as atenolol, nifedipine or hydrochlorothiazide. Any other chronic disease requiring chronic medication could be used.

**[0019]** The treatment of allergic conjunctivitis and rhinitis are also good

applications for the invention, e.g. using antihistamine and anti-allergy medication such as olopatadine and cromalyn sodium in or on the implant.

**[0020]** The advantage is that there would be no need for chronic pill-taking or drop taking. A once-per 3-6 month visit to the eye doctor would be all that is needed. Also the issue of non-compliance, a major impediment to successful treatment, would be avoided by the invention.

**[0021]** This list of active agents is not comprehensive in that many other agents can be used with the present invention. For example, a treatment for dry eye by topical cyclosporin is particularly interesting for administration by the present invention, but many other active agents can also be administered using the method and apparatus of the invention.

**[0022]** The invention is meant to embody all implants or devices which are implanted into the eye-lid canalicular puncta of the naso-lacrimal system with the goal of delivering drug to the eye or to the body.

**[0023]** The implant is inserted into either the inferior (lower) or superior (upper) punctum or possibly both. The apparatus is constructed so as to have a drug attached to one or both sides of the implant and an occlusive plug of some inert biocompatible material.

**[0024]** Depending on the desired therapy, the implant could be oriented in the punctal canal to deliver the drug either to the tear lake and thus the eye, or to the nasolacrimal system and thus the body's systemic circulation. The drawings illustrate only three embodiments of the punctal plug or implant delivery system of the invention.

**[0025]** While a specific embodiment of the invention has been shown and

described in detail to illustrate the application of the principles of the invention, it will be understood that the invention may be embodied otherwise without departing from such principles.